



ISIS-4824 (ISIC0005-100)

PATENT

REMARKS

I. Status

Upon entry of the amendments set forth herein, claims 16-27 will be pending. Claims 1-15 have been cancelled. Claims 16 and 23 have been amended. Claims 25-27 have been added. Support for the amendments and new claims can be found in the original claims and throughout the specification, such as in Examples 3-6. No new matter has been added.

II. Restriction Requirement

The Examiner has required restriction to one of the following two Groups:

I. Claims 1-15, drawn to an oral formulation, classified in Class 514, subclass 2 or Class 514, subclass 44; and

II. Claims 16-24, drawn to a method for enhancing the intestinal absorption of a drug in an animal comprising administering the formulation of invention I, classified in Class 514, subclass 2 and Class 514, subclass 44.

Applicants respectfully traverse the restriction requirement because it is improper.

M.P.E.P. 803 provides:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct invention.

For a restriction requirement to be valid, the Examiner must establish the following two criteria: (1) the existence of independent and distinct inventions, (35 U.S.C. 121); and (2) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P. 803).

The restriction requirement is improper because the Office Action has not shown that examining all the claims would constitute a serious burden. The subject matter of Groups I and II are closely related such that the examination of either Group will inevitably require the searching of subject matter common to the other Group. For example, the Examiner will be

required to search the art concerning the oral formulations in determining the patentability of the method claims. Accordingly, the subject matter of Groups I and II can be examined in a single application, resulting in economies to the Patent Office as well as the Applicants.

Because there would not be a serious burden to search the subject matter of both Groups I and II, the restriction requirement is improper. Accordingly, Applicants respectfully request reconsideration requirement.

Solely to satisfy 37 CFR 1.143, Applicants hereby provisionally elect, with traverse, Group II (claims 16-24) drawn to methods for enhancing intestinal absorption of a drug.

The Office Action further requires a provisional election of species. Applicants hereby provisionally elect a species relating to formulations comprising:

Drug: oligonucleotide

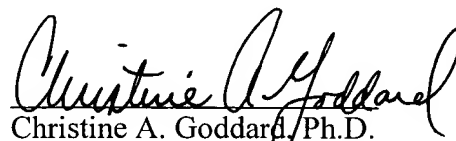
Penetration Enhancer: Capric acid

Bioadhesive: polyacrylic polymers.

Claims 16-27 are readable on the elected species.

It is Applicants' understanding that election of species is provisional, and that should the Examiner find no prior art that renders the species anticipated or obvious, the search will be extended to non-elected species to the extent necessary to determine patentability of the claim. (See, e.g., M.P.E.P. 803.02).

Respectfully submitted,



Christine A. Goddard/Ph.D.
Registration No. 46,731

Date: November 5, 2003

COZEN O'CONNOR

1900 Market Street
Philadelphia, PA 19103
(215) 665-2191 (phone)
(215) 701-2191 (fax)